Docket No.: KHAB 8076US
Date: September 14, 2001

In re application of: Bakulesh Khamar
Serial No.: 09/868,075

For: THE PROCESS FOR MANUFACTURING FORMULATION OF TOPICAL BETA BLOCKERS WITH IMPROVED EFFICACY

Box PCT
Commissioner for Patents
Washington, D.C. 20231

Sir:

Transmitted herewith is:

[X] A Petition to Revive Application For Patent Abandoned Unintentionally – 37 CFR 1.137(b)

[X] Preliminary Amendment, along with Specification Paragraphs and Claims Marked to Show Changes Following Preliminary Amendment

[X] Claiming Small Entity Status

[X] Information Disclosure Statement, Form PTO-1449 (4 references)

[X] Copy of Notification of Abandonment

[X] A check in the amount of $1120.00 is attached.

The Commissioner is hereby authorized to charge any additional fees or credit overpayment under 37 CFR 1.16 and 1.17 which may be required by this paper to Deposit Account 162201. *Duplicate copies of this sheet are enclosed.*

J. Philip Polster
Registration No: 24,739

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Bakulesh Khamar
SERIAL NO.: 09/868,075
FILED:
FOR: THE PROCESS FOR MANUFACTURING FORMULATION OF TOPICAL BETA BLOCKERS WITH IMPROVED EFFICACY

GROUP ART UNIT:
EXAMINER:
DOCKET NO.: 8076

U.S. National Stage of
International Application PCT/IB99/00378
IA Filing Date: 01 March 1999

Box PCT
Assistant Commissioner of Patents
Washington, D.C. 20231

September 14, 2001
St. Louis, Missouri

Sir:

PETITION TO REVIVE APPLICATION FOR PATENT ABANDONED UNINTENTIONALLY – 37 CFR 1.137(b)

The Notice of Abandonment dated 22 August 2001 has been received, and in response thereto applicant respectfully petitions for revival of the application for unintentional abandonment. The entire delay in paying the full U.S. Basic National Fee by 30 months (37 CFR 1.495(b)(2)) from the due date until the filing of this petition was unintentional.

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to, Assistant Commissioner for Patents, Washington D.C., 20231 on September 14, 2001

J. Philip Polster, Reg. No. 24,739

SEPT 14, 2001
Date

Abandonment occurred because applicant failed to pay the full amount of the national fee on his credit card. Applicant intended that the entire fee would be charged to his credit card. Promptly upon receipt of the notification of abandonment, applicant's undersigned attorney ascertained by telephone to the Office the reason for the abandonment and requested confirmation from the applicant that the abandonment was unintentional. This petition is being filed promptly upon receipt of that confirmation.

Applicant is a small entity.

The full filing fee ($500) for a small entity is enclosed herewith (code 961) together with the fee ($620) for this petition (code 241). Please charge any additional costs, or credit any overpayment to Account No. 16-2201.

If this petition is defective in any way, applicant's undersigned attorney urgently requests a telephone call at 314-872-8118, extension 426.

Respectfully submitted,

J. Philip Polster
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June 8, 2001
COURIER

To,
Assistant Commissioner of Patents,
United States Patent and Trademark Office
Box PCT,
Washington DC 20231, USA

FAX: 001 703 305 3230

Dear Sir,

Sub: Request for entry into national phase of PCT/IB99/00378 (published as WO 00/35439) in USA as elected office.

We have filed a patent application with PCT on March 4, 1999 and has been given International application no. PCT/IB99/00378. The International search report has been published (WO 00/35439). We have filed a demand for International Preliminary Examination, whose report is awaited. Now it has to enter national phase in USA.

Through this letter, I am making formal request to enter the national phase, for which I am enclosing the relevant forms duly filled.

For your reference, I am enclosing (a) copy of the Form Notice informing the applicant of the communication of the International application to the Elected Offices received from PCT office, Geneva (b) Copy of the publication and search report.

Kindly acknowledge the same.

Best Regards,

Khamar B.M.

Dr. Bakulesh M Khamar

Encl: as above.

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Bakulesh Khamar
SERIAL NO.: 09/868,075
FILED:
FOR: (as amended) FORMULATION OF TOPICAL BETA BLOCKERS WITH IMPROVED EFFICACY AND PROCESS FOR MANUFACTURING IT

GROUP ART UNIT:
EXAMINER:
DOCKET NO.: 8076

U.S. National Stage of
International Application PCT/IB99/00378
IA Filing Date: 01 March 1999

Box PCT
Assistant Commissioner of Patents
Washington, D.C. 20231

September 14, 2001

Sir:

PRELIMINARY AMENDMENT

Please amend the above-identified application before calculating the filing fee as follows:

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to, Assistant Commissioner for Patents, Washington, D.C. 20231 on September 14, 2001

J. Philip Polster

9/14/01
Date

SPECIFICATION

Page 1, first paragraph, change the title of the invention to read:

FORMULATION OF TOPICAL BETA BLOCKERS WITH IMPROVED EFFICACY AND PROCESS FOR MANUFACTURING IT

Page 1, lines 12-16 (fourth paragraph), substitute the following paragraph:

Beta-blockers are known to reduce I.O.P. mainly by reduction in aqueous secretion. This reduction in aqueous secretion is dose dependent. However, increasing the dosage beyond a point does not improve its capacity to reduce I.O.P. For timolol, levobunolol and betaxalol it is achieved at 0.5% concentration, for carteolol it is 1%, and for metipranolol it is 0.3%. Increasing concentration beyond this does not result in further reduction in I.O.P.

Page 3, lines 8-10 (fifth paragraph), substitute the following paragraph:

Beta-blockers described above can be timolol 0.5%, betaxolol 0.5%, levobunolol 0.5%, carteolol 1.0%, metipranolol 0.3%, or any other Beta-blocker which can reduce I.O.P in a therapeutic concentration.

Page 3, lines 11-12 (sixth paragraph), substitute the following paragraph:

Carbopol is a registered trademark for a family of resins which have been given the generic name "carbomer." The carbomer can be Carbopol 940, 932, 970 or others which form a gel in aqueous solution. The concentration of carbomer in the final formulation can be from 0.5% to 5%.

CLAIMS

1. (amended) A process of manufacturing a formulation of topical Beta blockers with improved efficacy comprising the following steps:

i) a. making aqueous solution of Beta-blocker with or without physiologically acceptable excipients, buffers and preservatives;

b. making a gel of known gel forming substance with or without physiologically acceptable excipients buffers and preservatives in a separate vessel;

ii) adding aqueous solution of Beta-blockers at step i (a) into a prepared gel of step i (b) while stirring slowly; and

iii) adjusting the pH and volume before finally autoclaving and packaging.

2. (amended) The process of claim 1 wherein the Beta-blockers are selected from the group of topical Beta-blockers used to reduce intraocular pressure consisting of Timolol, Betaxolol, Carteolol, and Metipranolol.

3. (amended) The process of claim 1 wherein the gel forming agent is a carbomer.

4. (amended) The process of claim 3 wherein the concentration of carbomer is from 0.5% to 5%.

5. (amended) The process of claim 1 in which physiologically acceptable buffers, excipients and preservatives are used.

6. (amended) The process of claim 1 wherein the pH of the formulation is finally adjusted to between 6.0 to 8.0.

7. (amended) The process of claim 1 wherein the formulation is autoclaved before packaging.

Cancel claim 8.

Add the following claims 9-15:

9. The process of claim 6 wherein the pH of the formulation is finally adjusted to between 6.5 and 7.5.

10. A formulation of topical Beta blockers with improved efficacy comprising a gel of Beta-blocker and a gel-forming substance.

11. The formulation of claim 10 wherein the Beta-blockers are selected from the group of topical Beta-blockers used to reduce intraocular pressure consisting of Timolol, Levobunolol, Betaxolol, Carteolol, and Metipranolol.

12. The formulation of claim 11 wherein the gel forming agent is a carbomer.

13. The formulation of claim 11 wherein the concentration of carbomer is from 0.5% to 5%.

14. The formulation of claim 11 further comprising at least one additional substance comprising a physiologically acceptable buffer, excipient or preservative.

15. The formulation of claim 11 having a pH of 6.0 to 8.0

REMARKS

The foregoing amendments to the claims eliminate multiple dependencies and remove a claim which is not in proper form under U.S. practice. An alternative limitation in claim 6 has been made the subject of new dependent claim 9.

New claims 10-15 are product claims.

The term "Carbopol" is a registered trademark for a family of resins which are high molecular weigh, allylpentaerythritol-crosslinked, acrylic acid-based polymers modified with C_{10}-C_{30} alkyl acrylates. These resins have been given the generic name "carbomer" by the USP-NF, British Pharmacopoeia, United States Adopted Names Council (USAN) and Cosmetic, Toiletries and Fragrance Association (CTFA). Thus, the generic name of Carbopol 940 is carbomer 940. The specification and claims have been amended to use the generic name.

It is believed that the foregoing amendment introduces no new matter into the application, and it is therefore requested that the amendment be entered.

Respectfully submitted,

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Bakulesh Khamar
SERIAL NO.: 09/868,075
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Box PCT
Assistant Commissioner of Patents
Washington, D.C. 20231

September 14, 2001

Sir:

SPECIFICATION PARAGRAPHS AND CLAIMS MARKED TO SHOW CHANGES FOLLOWING PRELIMINARY AMENDMENT

SPECIFICATION

———Beta-blockers are known to reduce I.O.P. mainly by reduction in aqueous secretion. This reduction in aqueous secretion is dose dependent. However, increasing the dosage beyond a point does not improve its capacity to reduce I.O.P. For timolol, levobunolol and ~~Betaxalol~~ betaxolol it is achieved at 0.5% concentration, for carteolol it is 1%, and for metipranolol it is 0.3%. Increasing concentration beyond this does not result in further reduction in I.O.P.

———Beta-blockers described above can be timolol 0.5%, ~~Betaxolol 0.5%, Levobunolol 0.5%, Cartelol 1.0%, metipruanolol~~

~~0.3%~~betaxolol 0.5%, levobunolol 0.5%, carteolol 1.0%, metipranolol 0.3%, or any other Beta-blocker which can reduce I.O.P in a therapeutic concentration.

~~Carbopol can be carbopol 940,932~~Carbopol is a registered trademark for a family of resins which have been given the generic name "carbomer." The carbomer can be Carbopol 940, 932, 970 or others which ~~forms~~form a gel in aqueous solution. The concentration of ~~carbopol in~~carbomer in the final formulation can be from 0.5% to 5%.

CLAIMS

1. (amended) A process of manufacturing ~~of~~ a formulation of topical ~~beta~~Beta blockers with improved efficacy comprising the following steps:

i) a. ~~Making~~making aqueous solution of Beta-blocker with or without physiologically acceptable excipients, buffers and ~~preservatives.~~preservatives;

b. ~~Making~~making a gel of known gel forming substance with or without physiologically acceptable excipients buffers and preservatives in a separate ~~vessel.~~vessel;

ii) ~~Adding~~adding aqueous solution of Beta-blockers at step i (a) into a prepared gel of step i (b) while stirring ~~slowly.~~slowly; and

iii) ~~Adjusting~~adjusting the pH and volume before finally autoclaving and packaging.

2. ~~A process as claimed in claim 1 wherein Beta-blockers can be selected from~~ (amended) The process of claim 1 wherein the Beta-blockers are selected from the

group of topical Beta-blockers used to reduce intraocular ~~pressure, e. g.~~pressure consisting of Timolol, Betaxolol, Carteolol, ~~Metipranalol.~~and Metipranolol.

3. ~~A process as claimed in claim 1 & 2 wherein gel forming agent can be carbopol.~~ (amended) The process of claim 1 wherein the gel forming agent is a carbomer.

4. ~~A process as in claim 1 to 3 wherein concentration of carbopol can be~~ (amended) The process of claim 3 wherein the concentration of carbomer is from 0.5% to 5%.

5. ~~A process as claimed in claim 1 to 4~~ (amended) The process of claim 1 in which physiologically acceptable buffers, excipients and preservatives are used.

6. ~~A process as claimed in claim 1 to 5 wherein pH of~~ (amended) The process of claim 1 wherein the pH of the formulation is finally adjusted to between 6.0 to 8.0 ~~preferably between 6.5 and 7.5~~.

7. ~~A process as claimed in claim 1 to 6 wherein~~ (amended) The process of claim 1 wherein the formulation is autoclaved before packaging.

THE PROCESS FOR MANUFACTURING FORMULATION OF TOPICAL BETA BLOCKERS WITH IMPROVED EFFICACY.

The present invention relates to a process of manufacturing a formulation of Beta-blockers with improved efficacy and tolerance. Beta-blockers are used as topical ophthalmic preparations for reducing intraoculer pressure.

The present invention is directed to manufacturing of a formulation containing Beta-blockers in such a way so that pressure lowering effects of Beta-blockers are improved. Beta-blockers are required to be used for a long time for reduction in I.O.P. Their prolonged use is associated with instability of tear film leading to dry eye. The present invention is also directed to manufacturing of a formulation containing Beta-blockers in such a way so that tear film is stabilized.

Beta-blockers are known to reduce I.O.P. mainly by reduction in aqueous secretion. This reduction in aqueous secretion is dose dependent. However, increasing the dosage beyond a point does not improve its capacity to reduce I.O.P. For timolol, levobunolol and Betaxalol it is achieved at 0.5% concentration for carteolol it is 1% and for metipranalol it is 0.3%. Increasing concentration beyond this does not result in further reduction in I.O.P.

The attempts made to improve its efficacy are not successful. In clinical situation when further reduction in I.O.P. is desired another drug like, Pilocarpine, Dipivefrin hydrochloride, Dorzdamide, Brimonidine, Latanoprost, etc. is added to it.

The formulations of Beta-blockers used are usually aqueous in nature.

There are sustained release preparations available for Beta-blockers. The formulation of pilocarpine in sustained release preparation is required to be doubled i.e. for I.O.P. reduction as much as 2% pilocarpine solution, 4% pilocarpine gel is required. Betaxolol is available as Betopitic-s and of timolol is Timoptic-XE. In both formulations vehicle used are different. With this it is possible to reduce concentration of Betaxolol used, but it is not possible to improve effect on I.O.P. Similarly, it is possible to reduce frequency of administration from twice a day to once a day with timoptic-XE. However, pressure lowering effect remains same. The formulations made with hydroxyl propyl methyl cellulose are found to be of no advantage compared to aqueous formulation.

Similarly, sustained release preparation of pilocarpine (Pilopine-HS gel) is also available. It contains Carbopol as a vehicle. The duration of action is prolonged but pressure reducing effect is reduced. To get the pressure lowering effect as much as aqueous solution, concentration of pilocarpine in sustained release preparation is required to be doubled i.e. for I.O.P. reduction as much as 2% pilocarpine solution, 4% pilocarpine gel is required.

The objective of present invention is to provide formulation of Beta-blockers with improved efficacy.

The further objective of present invention is to provide formulation of Beta-blocker which stabilizes the tear film.

The further objective of present invention is to provide a formulation of Beta-blockers which is effective after longer period of storage.

The further objective of present invention is it minimize/eliminate Beta-blocker entering systemic circulation.

The further objective of present invention is to increase compliance by reduction/ elimination of side effects of Beta-blockers.

The further objective of present invention is to provide formulation in a concentration which is known to provide maximum I.O.P. lowering effect in a conventional aqueous formulation.

Accordingly, there is provided a process of manufacturing formulation of topical beta blocker with improved efficacy which comprises of the following steps :

1. The aqueous solution of Beta-blocker is made which contains acceptable excipients, buffers and preservative in distilled water. The pH of this solution is adjusted to 7.0 to 7.5.

2. In a separate vessel Carbopol is dissolved into water and stirred well till gel is formed. Preservatives and buffers are added to it gradually while stirring. The pH of solution is adjusted to pH 6.5 to 7.5.

3. Solution containing Beta-blocker as formulated in step 1 is gradually added to the get as formed in step 2.

4. Volume is made up by adding distilled water as required.

5. pH is checked and adjusted as necessary to keep it in range of 7.0 $\pm$ 0.5.

Beta-blockers described above can be timolol 0.5%, Betaxolol 0.5%, Levobunolol 0.5%, Cartelol 1.0%, metipruanolol 0.3% or any other Beta-blocker which can reduce I.O.P in a therapeutic concentration.

Carbopol can be carbopol 940, 932 970 or others which forms gel in aqueous solution. The concentration of carbopol in final formulation can be from 0.5% to 5%.

The buffer which can be used, can be any, used in topical ophthalmic preparation e.g. dibasic sodium phosphate sodium phosphate mono basic etc.

The preservative can be EDTA, Benzyloconium chloride, Cetrimide or any other which can be used in ophthalmic topical preparation in a dosage recommended.

pH is usually acidic and needs to be adjusted by sodium hydroxide.

The final product is autoclaved and put into a sterile packaging.

Example of formulation

I. Timolol 0.5%

Timolol maleate	0.72 gm equivalent to 0.5 gm of timolol
Benzylconium chloride	0.0107 gm
Carbopol 940	2.0 gm
Sodium hyroxide to adjust pH	6.5 to 7.5
Water for injection	QS to make 100 ml.

II. Betaxolol 0.5%

Betaxolol hydrochloride	0.56 gm equivalent to 0.5 gm of Betaxolol
Benzylconium chloride	0.01 gm
Di basic sodium phosphate	0.05 gm
Sodium phosphate mono basic	0.025 gm
Di sodium EDTA	0.05 gm
Sodium chloride	0.30 gm
Propylene glycol	2.50 gm
Carbopol 940	2.00 gm
Water for injection	QS to make 100 ml of solution

The pharmaceutical composition so manufactured is evaluated for stability and efficacy.

The pharmaceutical composition so manufactured is evaluated at different test conditions of temperature and humidity (45° C, 37° C at 80% relative humidity and ambient temperature), for time interval extending upto 12 months.

The samples of formulation were taken for study.

The formulation of timolol 0.5% made as described (new formulation) was evaluated in healthy volunteers as well as in eyes having raised intraocular pressure.

In a single dose paralleled study timolol 0.5% eye drops (conventional formulation) were instilled in one eye and new formulation was instilled in the other eye of 11 patients. Timolol eye drops caused drop in I.O.P. by 23.49% while new formulation caused drop in I.O.P. by 38.7%.

In a single dose cross over study (10 eyes) new formulation as well as conventional formulation (eye drops) were instilled in same eye on different days, but at the same time of day. It was found that reduction in I.O.P. with conventional formulation was 22.36% while that with new formulations was 37.7%.

Thus improved efficacy of new formulation is established in healthy volunteers.

Similarly, in glaucomatous eyes (14), both formulations (conventional and new) were evaluated. Even in glaucomatous eyes the reduction in I.O.P. noticed was much more than that seen with conventional formulation. With conventional formulation it was 33.35% while with new formulation drop in I.O.P. was 44.4%.

The effect on reduction in I.O.P. seen in glaucomatous eyes was further evaluated by long term application in 14 eyes. It was found that effect is maintained even on long term application. The drop in I.O.P. in glaucomatous eyes was 44.4% at 15 days, 43.6% at one month and 43.6% at three months interval.

Thus new formulation was found to have improved efficacy in glaucomatous eyes. This improved efficacy was found to persist even on long terms application.

Like eye drops of timolol, increasing concentration of timolol in new formulation from 0.5% to 1.0%, further drop in I.O.P. was not seen. However, this resulted in increase in duration of its action.

When other antiglaucoma drugs were added to therapy in persons using new formulation it was found to reduce I.O.P. further. This further reduction in I.O.P. was as good as seen with combination of antiglaucoma drugs with timolol eye drops.

Similarly, when formulation with other Beta-blockers like, Betaxolol were made as per process described in this invention it was also found to cause further drop in I.O.P. compared to conventional formulation.

Traditionally made viscous formulation for use as topical ophthalmic preparations are known to cause disturbances in vision. However, none of the person in whom new formulation were used complained of visual disturbances 5 minutes after instillation of new formulation.

1. A process of manufacturing of formulation of topical beta blockers with improved efficacy comprising the following steps :

i) a. Making aqueous solution of Beta-blocker with or without physiologically acceptable excipients, buffers and preservatives.

b. Making a gel of known gel forming substance with or without physiologically excipients buffers and preservatives in a separate vessel.

ii) Adding aqueous solution of Beta-blockers at step i(a) into a prepared gel of step i(b) while stirring slowly.

iii) Adjusting the pH and volume before finally autoclaving and packaging.

2. A process as claimed in claim 1 wherein Beta-blockers can be selected from topical Beta-blockers used to reduce intraocular pressure, e.g. Timolol, Betaxolol, Carteolol, Metipranalol.

3. A process as claimed in claim 1 & 2 wherein gel forming agent can be carbopol.

4. A process as in claim 1 to 3 wherein concentration of carbopol can be from 0.5% to 5%.

5. A process as claimed in claim 1 to 4 in which physiologically acceptable buffers, excipients and preservatives are used.

6. A process as claimed in claim 1 to 5 wherein pH of formulation is finally adjusted to between 6.0 to 8.0 preferably between 6.5 and 7.5.

7. A process as claimed in claim 1 to 6 wherein formulation is autoclaved before packaging.

8. A process as claimed in claim 1 and substantially herein described in example I & II in the accompanying specification.

Please type a plus sign (+) inside this box → ☐

PTO/SB/01 (12-97)
Approved for use through 9/30/00. OMB 0651-0032
Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)

☐ Declaration Submitted with Initial Filing OR ☐ Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)

Attorney Docket Number	
First Named Inventor	Bakulesh M Khamar
COMPLETE IF KNOWN	
Application Number	/
Filing Date	
Group Art Unit	
Examiner Name	

As a below named inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

The process for manufacturing formulation of topical beta blockers with improved efficacy.

(Title of the Invention)

the specification of which
☐ is attached hereto
OR
☐ was filed on (MM/DD/YYYY) 03/04/1999 as United States Application Number or PCT International Application Number PCT/IB99/00378 and was amended on (MM/DD/YYYY) _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached? YES	NO
699/Bom/97	India	12/02/1997	☐	☐	☐
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

I hereby claim the benefit under 35 U.S.C. 119(e) of any United States provisional application(s) listed below.

Application Number(s)	Filing Date (MM/DD/YYYY)

☐ Additional provisional application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

Burden Hour Statement: This form is estimated to take 0.4 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box → ☐

PTO/SB/01 (12-97)
Approved for use through 9/30/00. OMB 0651-0032
Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

DECLARATION — Utility or Design Patent Application

I hereby claim the benefit under 35 U.S.C. 120 of any United States application(s), or 365(c) of any PCT international application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. 112, I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

U.S. Parent Application or PCT Parent Number	Parent Filing Date (MM/DD/YYYY)	Parent Patent Number (if applicable)
PCT/IB99/00378	12/02/1997	699/Bom/97

☐ Additional U.S. or PCT international application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

As a named inventor, I hereby appoint the following registered practitioner(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith: ☐ Customer Number [ ] → *Place Customer Number Bar Code Label here*
OR
☐ Registered practitioner(s) name/registration number listed below

Name	Registration Number	Name	Registration Number

☐ Additional registered practitioner(s) named on supplemental Registered Practitioner Information sheet PTO/SB/02C attached hereto.

Direct all correspondence to: ☐ Customer Number or Bar Code Label [ ] *OR* ☐ Correspondence address below

Name	J Philip Polster				
Address	Polster, leider, Woodruff & Lucchesil C				
Address	763, South Ballas Road				
City	St. Louis Missouri	State		ZIP	63141-8750
Country	USA	Telephone	314-872-8118	Fax	314-991-2178

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Name of Sole or First Inventor: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle [if any])	Family Name or Surname
Bakulesh Mafatlal	Khamar

Inventor's Signature	Chaman B.M.					Date	06/08/2001
Residence: City	Ahmedabad	State	Guj.	Country	India	Citizenship	Indian
Post Office Address	201, Ashadh, Vasundhara Colony,						
Post Office Address	Gulbai Tekra,						
City	Ahmedabad	State	Guj.	ZIP	380006	Country	India

☐ Additional inventors are being named on the ___ supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto